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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,587	09/16/2003	Sebastian Bohm	TGZ-021CP2	3678
959	7590	02/09/2006	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			DILLON JR, JOSEPH A	
			ART UNIT	PAPER NUMBER
			3651	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/664,587	BOHM ET AL.	
	Examiner	Art Unit	
	Joseph A. Dillon, Jr.	3651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 16-22, 24, 25, 27, 28, 30, 31, 33, 34 and 36-42 is/are pending in the application.
- 4a) Of the above claim(s) 21, 24, 25, 28, 31, 34, 38 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-20, 22, 27, 30, 33, 36, 37 and 39-41 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Objections*

1. Claim 22 is objected to because of the following informalities: the last phrase, as submitted, is in bold face type. This fails to conform to current U.S. practice.

Appropriate correction is required.

### *Double Patenting*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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3. Claims 16-20, 27, 30, 33, 37 and 39-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,808,075 and over claims 1-26 of U.S. Patent No. 6,877,528 in view of either Keck et al. (6,803,194) or Deiss et al. (6,057,111).

Both of these primary reference(s) disclose(s) all the limitation(s) of the indicated claim(s) but lack isolating based on phenotype.

With regard to claim(s) 17 & 18 they lack(s) where the cell population is a culture of isolated primary cells or a cell culture.

Both Keck et al. (6,803,194) and Deiss et al. (6,057,111) teach(es) isolating based on phenotype. For Keck et al. (6,803,194), see the first paragraph of the Summary of the Invention. For Deiss et al. (6,057,111), see the 13th paragraph of the Detailed Description.

With regard to claim(s) 17 & 18, Keck et al. (6,803,194) and Deiss et al. (6,057,111) either disclose(s) or suggest using a cell population is a culture of isolated primary cells or a cell culture.

With regard to the intended use language of the claim(s), i.e. for transplantation, for genetic modification, etc., as these are method claim(s), the examiner considers these limitation(s) positively recited. However, as the applicant has recited substantially identical method steps in each of the independent claim(s) and claim 16 is directed broadly to isolating cells for no specific intended use, the examiner takes these claim(s) as originally submitted, subsequently amended, as well as all original claim(s), to be evidence that the general method under prosecution can be applied to a plurality of

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intended uses, that the independent claim(s) under prosecution are obvious over each other, and stand and fall together. Should the applicant disagree with the examiner's position, the examiner invites the applicant to state as such on the record, recognizing that such a counter position raises the issue of further restriction.

It would have been obvious to modify U.S. Patent No. 6,808,075 or U.S. Patent No. 6,877,528 to provide/substitute isolating based on phenotype or using a cell population that is a culture of isolated primary cells or a cell culture in order to increase system applicability as taught by either Keck et al. (6,803,194) or Deiss et al. (6,057,111).

4. Claims 22 & 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,808,075 and over claims 1-26 of U.S. Patent No. 6,877,528 in view of either Keck et al. (6,803,194) or Bierre et al. (5,795,727).

Both of these primary reference(s) disclose(s) all the limitation(s) of the indicated claim(s) but lack isolating based on a cell cycle stage specific marker.

Both Keck et al. (6,803,194) and Bierre et al. (5,795,727) teach(es) isolating based on a cell cycle stage specific marker. For Keck et al. (6,803,194), see the first paragraph of the Summary of the Invention. For Bierre et al. (5,795,727), see the sixth paragraph of the Background Art.

It would have been obvious to modify U.S. Patent No. 6,808,075 or U.S. Patent No. 6,877,528 to provide/substitute isolating based on a cell cycle stage specific

marker in order to increase system applicability as taught by either Keck et al. (6,803,194) or Bierre et al. (5,795,727).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16-20,22,27,30,33,36,37 and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to all the claim(s) where such recitations are made, and by way of example claim(s) 16, the relationship between the system of line(s) 2 & the device of line(s) 5 is unclear. The examiner suggests indicating that the device is part of the system. The relationship between the mixture of line(s) 5 & the population of line(s) 3 is unclear. The examiner suggests consistent referencing. Additionally, the genesis of the pulse action is unclear and that the device is it's cause.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 16-20, & 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gohde et al. (4,756,427) in view of either Keck et al. (6,803,194) or Deiss et al. (6,057,111).

Gohde et al. (4,756,427) disclose(s):

- Cell sorting, title & column 1, line(s) 17;
- A microfluidic system, column 6, line(s) 61 & column 7, line(s) 7;
- A sorting channel 1;
- Pressure pulse deflection, 12, 11 & abstract;
- First & second outlets, 6 & 8.

Gohde et al. (4,756,427) lack(s) isolating based on phenotype.

With regard to claim(s) 17 & 18 Gohde et al. (4,756,427) lack(s) where the cell population is a culture of isolated primary cells or a cell culture.

It would have been obvious to modify Gohde et al. (4,756,427) to provide/substitute isolating based on phenotype or using a cell population that is a culture of isolated primary cells or a cell culture in order to increase system applicability as taught by either Keck et al. (6,803,194) or Deiss et al. (6,057,111).

9. Claims 22 & 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gohde et al. (4,756,427) in view of either Keck et al. (6,803,194) or Bierre et al. (5,795,727).

Gohde et al. (4,756,427) lack(s) isolating based on a cell cycle stage specific marker.

It would have been obvious to modify Gohde et al. (4,756,427) to provide/substitute isolating based on a cell cycle stage specific marker in order to increase system applicability as taught by either Keck et al. (6,803,194) or Bierre et al. (5,795,727).

***Conclusion***

10. Newly submitted claims 38 & 42 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim(s) 38 & 42 are directed to limitation(s) of Group I of the Restriction requirement of 9/14/04.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24,25,28,31 and 34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

11. With regard to claim(s) 21, this claim(s) is directed to method steps other than "isolating". This claim(s) was originally intended to have been withdrawn with claim(s) 24-25, 28, 31 & 41 in the Office action of 6/13/05 and was left under prosecution my mistake. The examiner regrets the oversight.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

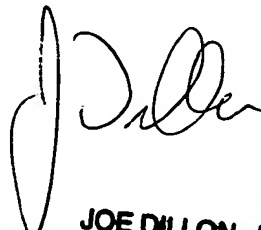
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph A. Dillon, Jr. whose telephone number is (571)272-6913. The examiner can normally be reached on 8-5:30, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene Crawford can be reached on (571)272-6911. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703)305-7687 for regular communications and (703)308-0552 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1134.



**JOE DILLON, JR.**  
**PRIMARY PATENT EXAMINER**